

MAR 15 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K043022

Device Name

Proprietary Name: Stryker Flexible CystoNephroscope
Common and Usual Name: Endoscope, Cystoscope, Nephroscope
Classification Name: Endoscope, Cystoscope, Nephroscope

This 510(k) summary of safety and effectiveness is being submitted in accordance with requirements of the SMDA 1990.

The Stryker Flexible CystoNephroscope is substantially equivalent in terms of safety and effectiveness to the currently marketed ACMI ACN-2 CystoNephroscope (K904797) and the Karl Storz 11001 DD Nephro-Fiberscope (K970427).

The Stryker Flexible CystoNephroscope is a modification of the currently marketed Stryker Flexible Ureteroscope, with changes to labeling, performance, materials, and intended use. The Stryker Flexible CystoNephroscope is a flexible fiberoptic endoscope with a working channel for irrigation and/or introduction of instruments and active deflection capability.

The Stryker Flexible CystoNephroscope is indicated for use during minimally invasive urological procedures through natural body orifices or through percutaneous access, and is intended for but not limited to, examining the urinary tract and the interior of the kidney, and, using additional accessories, performing various diagnostic and therapeutic procedures.

The Stryker Flexible CystoNephroscope conforms to the following voluntary safety and performance standards: IEC 60601-2-18 Particular Requirements for the Safety of Endoscopic Equipment, ISO 10993 Biological Evaluation of Medical Devices.

There are no significant technological or performance differences between the Stryker Flexible CystoNephroscope and the identified predicate devices, nor are there any new questions raised regarding safety or effectiveness, therefore, the Stryker Flexible CystoNephroscope is substantially equivalent to the identified predicate devices.

Contact:


Christopher L. Cook

11/1/04
Date:

Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2005

Mr. Christopher L. Cook
Regulatory Supervisor
Stryker Endoscopy
5900 Optical Court
SAN JOSE CA 95138

Re: K043022
Trade/Device Name: Stryker Flexible CystoNephroscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FAJ and FGA
Dated: February 16, 2005
Received: February 17, 2005

Dear Mr. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

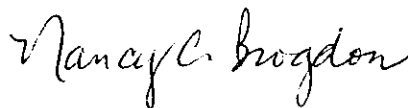
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: Stryker Flexible CystoNephroscope

K043022

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Spence
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K043022 Sub 1

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐